b.) Remarks

Claim 1 has been amended in order to recite the present invention with the specificity required by statute. Additionally, claims 8 and 12 are amended to correct their idiomatic usage. Accordingly, no new matter has been added.

In the Office Action, the previous rejections for obviousness were maintained for the reasons of record. Applicants note initially that the Examiner states at page 5 of the Office Action, lines 12-13 and page 18, lines 8-13 the cause of dimerization is not specified in the claims. In response, the claims are above amended instead to recite that formation of impurities in a pharmaceutical composition is suppressed as taught in Text Example 1 at specification pages 37-40.

As the Examiner is well-aware, the presently-claimed invention is a method for suppressing formation of impurities in a solid pharmaceutical composition containing a xanthine compound or pharmaceutically acceptable salt[2] by providing iron oxide in the solid formulation so as to suppress dimerization of such xanthine compound or salt.

Respectfully submitted, these features are not taught or suggested by the prior art.

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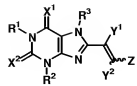
[2] Represented by formula (IA)



(IA)

Shimada does not teach or suggest any solid formulations of 8-styrylxanthines. Nor, therefore, does Shimada teach or suggest any stability issues of 8-styrylxanthines in solid formulations, let alone suppressing formation of impurities due to dimerization of the xanthine compound.

Shimada only discusses isomerization of 8-styrylxanthines when prepared as solutions. Thus, Shimada is irrelevant both as to (i) Applicants' solid formulation in addition to (ii) Applicants' prevention of dimerization therein. These deficiencies are not addressed by the secondary references.

Sako teaches that changes in drug release from a preparation containing polyethylene oxide can be prevented by adding yellow ferric oxide or red ferric oxide.[3] Thus, Sako relates to drug release and not to presenting impurities. These changes do not arise from dimerization and in any event, Applicants' claims do not recite polyethylene oxide.

Although Sako discloses a method for improving stability of polyethylene oxide in a formulation to avoid changes in drug release in preparations containing polyethylene oxide, Sako does not disclose a method for improving stability of any drug. Polyethylene oxide is not a drug, however, and does not at all render structurally obvious Applicants' 8-styrylxanthine.

Harrison discloses a controlled release preparation comprising a xanthine derivative and polyethylene oxide, but does not refer to formation of impurities of any

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[3] Sako states "As shown in Table 1, it was estimated that the drug release rate of the Comparative Example in which the preparation did not contain yellow ferric oxide and/or red ferric oxide would increase with exposure to light because the matrix erosion percentage increased." (Col. 7, lines 57-61).

drug, let alone preventing impurities formal by dimerization. Harrison *would* be relevant if Applicants' claims recited polyethylene oxide, but they do not.

In view of the above amendments and remarks, Applicants respectfully submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1 and 6-12 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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